

REMARKS

The Applicants wish to thank the Examiner for withdrawing the 35 U.S.C. 102(b), 102(e) and 103(a) rejections.

Oath/Declaration

The Examiner objects to the submitted 37 C.F.R. §1.63 oath as allegedly being non-compliant pursuant to 37 C.F.R. §1.52(c) because non-initialed and/or non-dated alterations were made to the oath.

The Applicants note the Examiner's objection to the oath as being non-compliant pursuant to 37 C.F.R. §1.52(c) and are still endeavoring to procure a new oath. However, this will require more time as several of the inventors reside in England and Ireland. Once again, the Applicants wish to assure the Examiner that once received, the new oath will be promptly submitted.

Amendments to the Specification

The Abstract was amended for grammatical reasons. The Applicants respectfully submit that the abstract is grammatically correct and request the withdrawal of the objection.

Amendments to the Claims

The Applicants respectfully ask the Examiner to replace all prior versions and listings of claims in the present application with the listing of claims currently provided. Claims 39 and 47 were amended. Claims 20-28, 32, 33, 38 and 40-46 were previously presented. Claims 1-19, 29-31 and 34-37 were cancelled in a previous reply. The Applicants state that all amended claims do not add new subject matter to the present specification.

Claim Objections

The Examiner has objected to Claims 39 and 47 for an alleged informality, indicating that "comprising" is not a verb. The Applicants have corrected the informality found in these two claims by replacing "comprising" with "comprises." The Applicants respectfully request withdrawal of the objection against Claims 39 and 47.

Rejection Pursuant to 35 U.S.C. §112, ¶2 Indefiniteness

The Examiner has rejected Claims 20-28, 32-33 and 38-47 as allegedly being indefinite under 35 U.S.C. §112, ¶2. The Applicants respectfully ask for reconsideration under 37 C.F.R. §1.111.

With respect to Claims 20-28, 32-33, 38-39 and 41-47 the Examiner contends that the phrase "a peptide comprising a non-native clostridial neurotoxin protease cleavage site" is unclear. Specifically, the Examiner argues that this phrase can mean a protease cleavage site which is not recognized by a clostridial protease, a protease cleavage site not normally present in clostridial toxins or a cleavage site not recognized by a specific host cell. According to MPEP 2173.02 the definiteness requirement is satisfied when a reasonable degree of clarity and particularity defines the claimed subject matter. The Applicants respectfully submit that the term

“non-native clostridial neurotoxin protease cleavage site” is a clear and precise term, and therefore definite.

First, the term “native” means constituting the original substance or source of something; found in nature especially in an unadulterated form, see, *e.g.*, Merriam-Webster Online; and *Webster’s Third New International Dictionary of the English Language*, unabridged, Merriam-Webster, Inc, (1993). These references further indicates that the antonym of “native” is “non-native”. Therefore, a “non-native clostridial neurotoxin protease cleavage site” is a protease cleavage site not originally found in a Clostridial neurotoxin. Thus, the plain meaning of the term “non-native clostridial neurotoxin protease cleavage site” would be clear and precise to one skilled in the art.

Second, whether the non-native clostridial neurotoxin protease cleavage site is not cleaved by a clostridial protease or is not cleaved by a specific host cell protease is immaterial because these characterizations refer to attributes that a “non-native clostridial neurotoxin protease cleavage site” may or may not have, see the present specification at, *e.g.*, page 16, lines 5-13; page 17, line 26 through page 18, line 2; page 18, lines 6-12; and page 24, lines 12-23. Thus, the fact that a “non-native clostridial neurotoxin protease cleavage site” is cleaved by a Clostridial toxin, not cleaved by a Clostridial toxin, cleaved by a specific host cell protease, or not cleaved by a specific host cell protease does not alter in any way the clear and precise meaning of this cleavage site as a protease cleavage site not originally found in a Clostridial neurotoxin. Therefore, the Applicants respectfully submit that Claims 20-28, 32-33, 38-39 and 41-47 are clear and precise and request withdrawal of the 35 U.S.C. §112, ¶2 indefinite rejection.

With respect to Claim 32 the Examiner contends that there is insufficient antecedent basis for the limitation “inserting the plasmid of any of claims 20-28, 31 or 38” because Claims 20-28 and 38 recite “nucleic acid molecule” and not “plasmid.” The Applicants have amended Claim 32 by replacing “plasmid” with “nucleic acid molecule.” The Applicants respectfully submit that Claim 32 now has proper antecedent basis and request withdrawal of the 35 U.S.C. §112, ¶2 indefinite rejection.

With respect to Claim 33 the Examiner contends that there is insufficient antecedent basis for the limitation “the plasmid of either of claims 21 or 22” because Claims 21 and 22 recite “nucleic acid molecule” and not “plasmid.” The Applicants have amended Claim 33 by replacing “plasmid” with “nucleic acid molecule.” The Applicants respectfully submit that Claim 33 now has proper antecedent basis and request withdrawal of the 35 U.S.C. §112, ¶2 indefinite rejection.

CONCLUSION

For the above reasons the Applicants respectfully submit that the claims are in condition for allowance, and the Applicants respectfully urge the Examiner to issue a Notice to that effect. Please use Deposit Account 01-0885 for the payment of the extension fees or any other fees due in connection with the current response.

Respectfully submitted,



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